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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,672	06/01/2001	Ryota Sugimoto	018961-054	8651

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EXAMINER	
MATHEW, FENN C	
ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/870,672	Applicant(s) SUGIMOTO, RYOTA	
	Examiner Fenn Mathew	Art Unit 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 6, 10, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Starck et al. (U.S. Patent No. 5,876,449). Starck discloses an implantable tubular device formed substantially tubular (see abstract, line 3), and having a deformable portion formed on a peripheral surface thereof, with said deformable portion forming a predetermined angle with respect to an axial direction (see figs. 4a & 4b) of said device and being easy to deform in comparison with a remainder part of said device (column 5, lines 1-12), the deformable portion being plural in number (see figs. 3a-3b), and being entirely on the tubular device.

3. Referring to claim 3, Starck discloses an implantable device wherein the deformable portions include of a groove formed on an inner and outer surface of the device. (See figs. 4a, 4b).

4. Referring to claim 6, Starck discloses deformable portions are so formed that when the deformable portions are prolonged, the deformable portion continuously goes around a periphery of the device (inherently).

5. Referring to claim 10, Starck discloses a device wherein the device consists of a stent. (See abstract, line 1).

6. Referring to claim 20, Starck discloses the device consists of a stent with a frame structure with the deformable portion being located entirely on the structure.

7. Claims 2, 21, and 22, are rejected under 35 U.S.C. 102(e) as being anticipated by Boatman et al. (U.S. Patent No. 6,464,720). Referring to claim 2, Boatman discloses an implantable tubular device formed substantially tubular and having a diameter so the device can be inserted into a lumen, and capable of dilating radially upon application of a force acting radially outwardly from an interior of the tubular body, the device comprising a plurality of wavy annular members each formed of a wavy element an arrange din an axial direction of the device, connection portions each connecting the wavy annular members to each other in the axial direction of the device, wherein the wavy annular members have a free bent portion not connected to other wavy annular members, a deformable portion (thinner portion of the free bent member) forming a predetermined angle with respect to the axial direction of the device and more easily deformed than a remainder of the device, deformable portion being formed on one of the free bent portions in such a way that the deformable portion crosses the wavy annular member (in the circumferential direction).

8. Referring to claim 21, Boatman discloses the device consists of a stent with a frame structure with the deformable portion being located entirely on the structure.

9. Referring to claim 22, Boatman discloses an implantable device wherein the deformable portions include a groove (thinner portion inherently forms groove) formed on an inner and outer surface of the device.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 4-5, 7, 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449).

12. Referring to claim 4, the feature of the specific depth of the groove being set to 5-50% of the thickness of the device is a matter of obvious design choice.

13. Referring to claim 5, the feature of having the deformable portions form a 20-90 degree angle with the axial direction of the device is a matter of obvious design choice.

14. Referring to claim 7, Starck et al., disclose the claimed invention except for the angle at which the deformed portion with respect to the axial direction, which when stretched out creates a spiral on the periphery of the device. It would have been an obvious matter of design choice to have the deformed portions form an acute angle with respect to the axial direction in such a manner that when the device was stretched out, a spiral was formed around the

periphery since applicant has not disclosed that having the deformable portions form a spiral periphery when the device is prolonged, solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with modified embodiment described above in claim 6.

15. Referring to claim 9, the feature of having the interval between the deformable portions in the axial direction in the range of 0.01 – 1 mm, is a matter of obvious design choice within the level of knowledge of one with ordinary skill in the art.

16. Referring to claims 11-12, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore this limitation has not been given patentable weight. The skilled artisan would choose a manner in which to form the device based on suitability and desired result.

17. Referring to claim 13, the feature of having groove depth set to 1-99% thickness of the device is a matter of obvious design choice within the knowledge of one with ordinary skill in the art.

18. Claims 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449) in view of Alt et al. (U.S. Patent No. 5,788,979). Starck et al., disclose the claimed invention except for having the device carrying a medicine, bioprosthetic material, or a biosynthesis material. Alt et al. teach a medicinal coating (column 8) that can be used for a stent (column 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Starck et al. with the medicinal coating taught by Alt et al. in order to deliver

medicine to areas in the body once the device has been implanted within the body.

19. Referring to claim 19, Starck et al., as modified by Alt et al., discloses a medicine containing a pharmaceutical consisting of an antibiotic. (Alt et al. column 8, lines 25-27).

20. Claims 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449) in view of Alt et al. (U.S. Patent No. 5,788,979). Starck et al., disclose the claimed invention except for having at least one part of the outer surface coated with a coating material made of a biocompatible material, a biodegradable material or a synthetic resin. Alt et al. disclose a coating comprising a biodegradable material (column 6, lines 59-64), which can be used for a stent (column 6, line 1).). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Starck et al. with the coating taught by Alt et al. in order to provide a more biocompatible implant that will not cause harm during degradation.

21. Referring to claim 17, Starck et al. as modified by Alt et al., discloses a coating that carries a medicine (column 8).

22. Referring to claim 18, Starck et al. as modified by Alt et al., discloses a coating material formed of a biodegradable material to which a medicine is added (column 8).

23. Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Starck et al. (U.S. Patent No. 5,876,449) in view of Alt et al. (U.S. Patent No.

5,788,979). Starck et al., disclose the claimed invention except for having at least one part of the outer surface of the deformable portion coated with a coating material made of a biocompatible material, a biodegradable material, or a synthetic resin. Alt et al. teach a biodegradable coating which can be used for a stent. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Starck et al. with the coating taught by Alt et al. on the outer surface of the deformable portion in order to provide a more biocompatible implant that will not cause harm during degradation.

24. Claims 23-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Boatman et al. Referring to claim 23, the feature of the specific depth of the groove being set to 5-50% of the thickness of the device is a matter of obvious design choice.

25. Referring to claim 24, the feature of having the interval between the deformable portions in the axial direction in the range of 0.01 – 1 mm, is a matter of obvious design choice within the level of knowledge of one with ordinary skill in the art.

26. Referring to claim 25-26 the method of forming the device is not germane to the issue of patentability of the device itself. Therefore this limitation has not been given patentable weight. The skilled artisan would choose a manner in which to form the device based on suitability and desired result.

27. Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boatman et al. (U.S. Patent No. 6,464,720) in view of Alt et al. (U.S. Patent

No. 5,788,979). Referring to claim 27, Boatman discloses the claimed invention except for the implantable device carrying a medicine, a bioprosthetic material or a biosynthesis material. Alt et al. teach a medicinal coating (column 8) that can be used for a stent (column 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Boatman with the medicinal coating taught by Alt et al. in order to deliver medicine to areas in the body once the device has been implanted within the body.

28. Referring to claim 28, Boatman discloses the claimed invention except for having at least one part of the outer surface coated with a coating material made of a biocompatible material, a biodegradable material or a synthetic resin. Alt et al. disclose a coating comprising a biodegradable material (column 6, lines 59-64), which can be used for a stent (column 6, line 1).). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Boatman with the coating taught by Alt et al. in order to provide a more biocompatible implant that will not cause harm during degradation.

29. Referring to claim 29, Boatman discloses the claimed invention except for having at least one part of the outer surface of the deformable portion coated with a coating material made of a biocompatible material, a biodegradable material, or a synthetic resin. Alt et al. teach a biodegradable coating which can be used for a stent. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device disclosed by Boatman with

the coating taught by Alt et al. on the outer surface of the deformable portion in order to provide a more biocompatible implant that will not cause harm during degradation.

30. Referring to claim 30, Boatman, as modified by Alt in claim 30, discloses the coating material carrying a medicine.

31. Referring to claim 31, Boatman, as modified by Alt in claim 31, discloses the coating material being formed of a biodegradable material, and carrying a medicine.

Response to Arguments

32. Applicant's arguments filed 11/5/2002 have been fully considered but they are not persuasive. Applicants arguments concerning claims 11 and 12 have been considered, however, as mentioned above, the method of forming the device is not germane to the patentability of the device itself, therefore the limitation has not been given patentable weight. Regarding claim 1, Starck shows a plurality of deformable portions on the implantable device. The limitation of the deformable portion being entirely located on the device has been considered with the broadest reasonable interpretation. The cut-outs define a deformable portion (thinner cross-section).

33. Applicant's arguments with respect to claim 2 have been considered but are moot in view of the new ground(s) of rejection. Boatman discloses the claimed limitations. Applicant has not made clear how the free bent portion crosses the wavy annular member. Therefore, using the broadest reasonable

interpretation, the free bent portion crosses a pair of annular members in the axial direction.

Conclusion

34. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hilaire et al.	U.S. Patent No. 6,416,543
Jacobsen et al.	U.S. Patent No. 6,063,101
Thompson	U.S. Patent No. 6,254,631
Wu et al.	U.S. Patent No. 6,254,632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

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